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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,986	09/30/2003	Paul J. Bobrowski	PHMC0745-020	4991
26948	7590	03/15/2004	EXAMINER	
ELLIS & VENABLE, PC 101 NORTH FIRST AVE. SUITE 1875 PHOENIX, AZ 85003			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/674,986	Applicant(s) BOBROWSKI, PAUL J.	
	Examiner Ray Henley	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 5, 11 AND 12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/30/2003</u> . | 6) <input type="checkbox"/> Other: ____ |

CLAIMS 1-16 ARE PRESENTED FOR EXAMINATION

Applicant's Information Disclosure Statement filed September 30, 2003 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449 (3 pages), the cited references have been considered.

Claim Objections

Claim 5 is objected to because of the following informality: a comma appears at line 2 after the term "of". Also, claim 8 appears to be grammatically incorrect and should have the phrase ---plants of the--- inserted before "family" at line 1. Appropriate correction is required.

Claims 11 and 12 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The recitation of the intended mechanism of action in these claims fails to impart any further physical or otherwise material limitation to the product of the claim from which they depend.

With respect to the latter objection, applicant is required to cancel the claims, amend the claims to place them in proper dependent form, or rewrite the claims in independent form.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1614

Claims 1 and 16 are indefinite as being incomplete for omitting an essential step, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is that after the “settling” step and before the “evaporating” step, there must be a step of separating the combination of resolved, distinct phases produced by the “settling step”.

In claim 1, the use of the term “lipidic” is confusing because its common meaning would be that which is of a fat or lipid material and applicant also using the term “lipophilic” in claim 1 to apparently indicate a different, distinct material. It is suggested that applicant employ terms from the present specification in order to particularly point out that material which resides in the aqueous layer of the “settling” step.

Claim 6 recites the limitation of “drying” in the method of claim 1. However, there is insufficient antecedent basis for this limitation in claim 1. Also, in claims 9 and 10, the limitation “the starting oxindole alkaloids content..” is recited but this finds no antecedent basis in claim 8.

Claims 8-10 are further considered indefinite because the amount of the oxindole alkaloid is expressed in terms of a material that is not a component of the extract itself, i.e., the “dried Rubiaceae plant material decoction” of claim 8 and “starting oxindole alkaloids content...” of claims 9 and 10.

In order to overcome this point of rejection, it is suggested that applicant cancel claims 9 and 10 and rewrite claim 8 to read:

“8. The extract produced by the method of claim 1 wherein said extract contains an oxindole alkaloid content of less than 0.3 mg/g.” (See the present specification at page 9, lines 18-19).

Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting reference to an essential element. See MPEP § 2172.01. The omitted element is that which is present in a biologically active amount, i.e., the phrase “comprising a biologically active amount to...” is incomplete.

Finally, respecting claim 15, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 15 recites the broad recitation “arthritis” (line 2), and the claim also recites “(both osteoarthritis and rheumatoid)” which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1614

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In particular, the term "Rubiaceae" as is used throughout the claims and the term "lipidic" as in claims 1 and 16 do not appear anywhere in the specification as filed at pages 1-10.

This rejection may be overcome simply by amending the specification as appropriate to include these phrases. This is proper because the claims as originally filed are considered to be a part of the disclosure as originally filed and as such, no new matter would be introduced by amending the specification as suggested above.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for extracting, extracts and methods of reducing the alkaloid content in an extract from plants of the family Rubiaceae which are of the genus *Uncaria*, does not reasonably provide enablement for such methods and extracts involving plants of the family Rubiaceae in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.

Art Unit: 1614

- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

1) Nature of the invention.

Claims 1-16, all the claims in the application, are directed to methods for extracting, extracts and methods of reducing the alkaloid content in an extract from plants of the family Rubiaceae. Applicant's specification, however, is directed solely to plants of the genus *Uncaria* (which belong to the family Rubiaceae).

2) State of the prior art.

As shown in the "Medical Botany" reference at page 509, second column under the heading "Rubiaceae", there is known to be a plethora of genera under the family Rubiaceae. Also, while in applicant's present invention, compounds which are extracted from *Uncaria* plants have anti-inflammatory and antioxidant activity, it is shown at pages 278-279 of the Medical Botany reference that not all of the plants in the Rubiaceae possess such compounds. In particular, the *Cephaelis acuminata* (which also belongs to the Rubiaceae family) possesses emetic compounds.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. However, given the state of the art as set forth above, the artisan is would not have expected all genera under the family Rubiaceae to be similarly useful.

4) Level of predictability in the art.

Insofar as the different genera of plants in the family Rubiaceae would not be expected to possess the same or similar compounds, methods of extraction which pertain to one genus would not generally be thought to apply to another genus. The same would hold true for the extracts from the different members of the Rubiaceae family because one would not expect that all would contain the same compounds which would possess the same activity.

5) Amount of direction and guidance provided by the inventor.

The specification only contains guidance and direction which is specific to the genus *Uncaria*.

6) Existence of working examples.

Applicants' specification at pages 5-8 contains working examples of extraction methods and biological activity which are specific to the genus *Uncaria*.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible genera of plants within the Rubiaceae family.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. Applicants have failed to provide guidance and information to allow the skilled artisan to practice an extraction method and obtain an extract having particular biological activity except for extractions and processes of extraction using the genus *Uncaria*. Given the level of predictability in the art as explained above in section "4)", the state of the art and the breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation; see *In re Armbruster* 185 USPQ 152 CCPA 1975.

Art Unit: 1614


Accordingly, for the above reasons, the claims are deemed to be properly rejected and none are allowed.

The Castillo et al. reference cited by the Examiner and not relied upon is cited to show the general state of the art for the use of an herbal extract composition which may contain, *inter alia*, an extract from *Uncaria tomentosa*, for the treatment of Alzheimer's disease and other amyloidoses.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Ray Henley
Primary Examiner
Art Unit 1614

Mar.10, 2004